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REVISED MEMORANDUM

TO: Commissioners

FROM: Eileen Fleck E.F.
Chief, Acute Care Policy and Planning

DATE: July 16, 2015

RE: Staff Recommendation for Proposed Permanent Regulations: State Health Plan for Cardiac Surgery and Percutaneous Coronary Intervention Services (COMAR 10.24.17); Analysis of Comments Received

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Maryland Health Care Commission (MHCC) staff is requesting that the Commission adopt as proposed permanent regulations a replacement COMAR 10.24.17: State Health Plan Chapter for Cardiac Surgery and Percutaneous Coronary Intervention Services ("Chapter"). Initial draft amendments to the Chapter were posted for informal public comment on April 17, 2015 with comments accepted through May 8, 2015. Seven individuals or organizations commented on this early draft. A copy of these informal comments is available on the MHCC web site.[1]

Commission staff discussed the comments received with members of the Commission's Cardiac Services Advisory Committee (CSAC) at a meeting held on May 13, 2015. Staff then revised the draft Chapter based on the informal comments, discussion by the CSAC, and additional internal staff review. As a result of changes to the definition of cardiac surgery, specifically the list of ICD-9 codes included, and the replacement of many references to cardiac surgery with open heart surgery, Staff decided to again post draft amendments to the Chapter for informal public comment on June 18, 2015 with comments accepted through July 6, 2015. Staff received comments from six individuals or organizations during this comment period. A copy of these comments is available on the MHCC website.[2]

[1] http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_shp/hcfs_shp.aspx
[2] http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_shp/hcfs_shp.aspx

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Following the posting of draft amendments to the Chapter, the Division of State Documents informed Commission staff that due to the number of changes (many of which involved minor formatting and word changes), amendments should be processed as repealing and replacing the Chapter. A summary of the informal comments received and Staff's response to these comments is presented below. In addition, other substantive changes that stem from internal staff review are explained. Attached is a copy of the draft proposed Chapter that Staff recommends the Commission adopt as proposed permanent regulations (Appendix 1).

Staff Response to Comments Received and Description of Additional Changes

.03 Issue and Policies

Commission staff recommends that the health planning region referred to as "Eastern" in the current Chapter is more appropriately labeled "Eastern/Lower Shore." Commission staff updated the discussion of the new waiver model because it referred what (at the adoption of the existing Chapter) were anticipated actions of the Commission, the Health Services Cost Review Commission, and/or hospitals. The text was either deleted or updated to reflect present status. Staff also made formatting changes to the footnotes in this section.

.04 Commission Program Policies

Staff made minor corrections in this section such as replacing the article "a" with "The" in three places and replacing a reference to "section .05" with "Regulation .05." Staff also changed a reference to "cardiac" surgery in Paragraph .04B(1)(b) to "open heart" surgery. This change is consistent with a discussion by the CSAC that the volume standards for cardiac surgery programs should be based on open heart surgery, rather than a broader list of cardiac surgery procedures. The rationale for this proposed change is that the purpose of the volume standards for cardiac surgery programs is to promote quality programs and to have sufficient volume at cardiac surgery programs to allow for a more accurate and timely assessment of the quality of programs. The research that supports the volume standards of 100 and 200 open heart cardiac surgery cases is primarily based on CABG procedures specifically, and the inclusion of other types of cardiac surgery procedures requiring a different set of skills could dilute the intent of the volume standard.

.05 Certificate of Need Review Standards for Cardiac Surgery Programs

Staff replaced references to "cardiac" surgery with "open heart" surgery throu ghout Regulation .05. As noted above, these changes were discussed by the CSAC and are consistent with the goal of promoting quality programs. Staff also updated references to Regulation .08, replacing it with reference to .10 because the text was moved after the addition of standards for external and internal peer review. For the impact and financial feasibility standards used to evaluate Certificate of Need applications for a new cardiac surgery program, Staff concluded that it is still appropriate to reference cardiac surgery because the costs and revenue for cardiac surgery programs logically should be evaluated based on all cardiac surgery cases performed.

.06 Certificate of Conformance Criteria.

In response to draft amendments to the Chapter that were posted in April for informal comment, MedStar Health commented that the language in Subsection .06A(5) is not consistent with similar language in Subsection .07D(5). In addition, Dr. Julie Miller recommended that external review of primary PCI programs be maintained because in certain circumstances it may be appropriate to consider cardiac surgery for such patients. Frederick Memorial Hospital (FMH) also commented that primary PCI cases should be reviewed for evaluating programs and for evaluating individual physicians.

In response to draft amendments to the Chapter posted in June for informal comment, Lifebridge Health commented that the issue of internal and external review is confusing in Paragraphs .06A(5)(c) and (d). It proposed that internal review of all STEMI PCI cases be required as part of the multidisciplinary committee process that is already outlined in the regulations.

Staff Response

Staff agrees that the language in Subsection .06A(5) should be consistent with Subsection .07D(5) and updated the language accordingly in the second draft posted for informal comment. In addition, Staff removed the requirement for external review of STEMI cases, in effect removing the requirement for external review of primary PCI programs, based on feedback from CSAC members at the March 2015 meeting. A majority of CSAC members favored this change because they expected very few STEMI cases would be deemed inappropriate and the impetus for the external peer review requirement was physicians inappropriately performing elective PCI procedures on patients. Based on the consensus of CSAC members, Staff concluded that no changes are required to address the recommendation of Dr. Miller and FMH.

In the draft amendments to the Chapter posted in June for informal comment, Staff added language in Subsection .06A(8) stating that a hospital granted a Certificate of Conformance for primary PCI services shall agree to comply with the requirements for a Certificate of Ongoing Performance, as a condition of the Certificate of Conformance. This language was added based on internal review by Staff. Similar language was also added in Subsection .06B(7) regarding elective PCI services.

Staff agrees that hospitals should perform internal case review as part of the multidisciplinary committee process, as is provided in the Chapter. Staff anticipates that such reviews will focus on cases with morbidity and mortality and cases with excessive door-to-balloon times or cases that meet other criteria determined by hospital administrators. However, a hospital is not required to review all STEMI cases. Although some hospitals have reported to Staff that all PCI cases are reviewed or all STEMI cases are reviewed, Staff concludes that such a requirement may be regarded as burdensome, given the other case review requirements included in the Chapter. The requirement for an internal or external review of 10 cases or 10 percent of an interventionalist's cases annually in Paragraph .06A(5)(c) is a way to assure that programs are evaluating themselves, and the requirement in Paragraph .06A(5)(d) assures that programs evaluate the performance of individual interventionalists at least annually. However, upon further review, Staff concludes that an annual requirement for internal or external review of

individual interventionalists' PCI cases is sufficient to accomplish the same goal and has revised the text accordingly.

.07 Certificate of Ongoing Performance

With regard to draft amendments to the Chapter posted in April 2015 for informal public comment, MedStar Health commented that in Sections .07C(4) and .07D(5) MHCC needs to clarify and reorganize the requirements. FMH also commented that the requirements for peer review are unclear. Meritus specifically asked whether cases with major adverse cardiovascular events (MACE) should be included for internal review in addition to 10 percent of randomly selected cases.

MedStar Health noted that in Sections .07C(4) and .07D(5), there are requirements for annual submission of a report to the Commission describing quality assurance activities, and questioned what information must be included and why it must be submitted annually when Certificates of Ongoing Performance will be granted for multiple years. MedStar Health questioned the requirements for hospitals to conduct staff meetings every other month for case review and monthly meetings for primary PCI system reviews. MedStar Health also questioned why the Commission would dictate how hospitals hold the required meetings by dictating the content and staff composition of these meetings. It also commented that the requirement for reviews of interventionalists are unclear as to when annual and semi-annual review are required. MedStar Health stated that internal processes, including internal peer review policies are thoroughly detailed by the Joint Commission and internal bylaws and do not require another layer of regulatory requirements. PRMC requested that a hospital be exempt from the external review process, if it is actively under a corporate integrity agreement.

With regard to the revised draft amendments posted in June 2015 for informal public comment, PRMC commented that the exemption from external and internal case review included in Paragraph .07C(4)(h) should also be noted in Section .07D. In addition, PRMC and MedStar Health both commented that a schedule for applications for Certificates of Ongoing Performance should be published annually. MedStar Health also commented that the frequency of renewals should be specified.

PRMC also commented that duplication of performance measures already required for hospitals that participate in the MIEMSS Cardiac Interventional Center designation and Maryland Cardiac Surgery Quality Initiative should be avoided. With regard to reporting requirements, MedStar Health commented that the MHCC should further assess the information that is available through the two national registries in which hospitals participate and provide duplicate information to the MHCC and reduce additional State reporting requirements. The University of Maryland Medical System (UMMS) commented that MHCC should continue efforts to streamline reporting requirements. Similarly, Lifebridge Health expressed concern about reporting requirements. It also expressed concern that institutions will be requested to submit individual patient records to MHCC in addition to the information submitted to the ACC-NCDR registry and the duplicate information submitted to MHCC.

MedStar Health and Lifebridge Health both commented that the requirements for internal and external review should be streamlined. Lifebridge Health specifically cited Paragraphs .07C(4)(c) and (d) as confusing, noting that .07C(4)(c) refers to external review and .07C(4)(d) refers to external or internal review. Lifebridge Health also proposed a minimum of five cases or 10 percent of cases, rather than 10 cases or 10 percent of cases for reviews of individual operators who perform PCI services. PRMC commented that peer review requirements should be clarified. UMMS commented that the requirement for an external review of five percent of randomly selected cases serves the objectives of the review process well. However, UMMS views the requirement for internal or external review of 10 percent or 10 cases, whichever is greater, for individual interventionalists as an undue burden whether conducted internally or externally. UMMS noted that while an internal review is less expensive, the time required is a burden and limits time for review of cases with complications or unusual cases. UMMS recommended retaining the threshold at five percent.

Lifebridge Health commented that the primary outcome measurement that will be assessed in the 30-day mortality rates following PCI. He noted that this information is currently not included in the ACC-NCDR registry. Lifebridge Health stated that the goal of using such rates is ambitious and suggested that MHCC focus on hospital mortality rates, contrast nephropathy, bleeding, and composite endpoint including death, emergency CABG, stroke, and repeat target vessel revascularization. He noted that all of these data are available through participation in the ACC-NCDR registry.

Dr. Yuri Deychak suggested that the continuing medical education (CME) requirement be revised. He noted that most cardiology subspecialty certification require 15 CME hours every three years and 30 CME hours in interventional cardiology may be difficult for interventional cardiologists with subspecialty certification to achieve.

Staff Response

Staff eliminated the requirement for an annual report on quality assurance activities, replacing it with a requirement for a hospital to certify that the hospital fully complies with each requirement for conducting and completing quality assurance activities specified in the Chapter and clarifying that the quality assurance activities will be evaluated through the Certificate of Ongoing Performance process. In the draft amendments posted in April 2015, Staff added the options for external review of interventionalists and more frequent reviews in order to give hospitals greater flexibility, instead of requiring annual internal review. Staff made also made other minor changes to clarify this intent. The meeting requirement for conducting internal case review at least every other month and monthly meetings for review of the PCI system are included in the current Chapter and earlier Chapters for at least ten years. The CSAC discussed the required meetings for internal case review, and the consensus of the CSAC was that such requirements are reasonable.

Staff added language to permit an exemption from internal and external review in response to PRMC's comments on the draft amendments posted in April 2015. In response to PRMC's subsequent comments regarding the exemption from external and internal review for primary PCI services, Staff reviewed the language cited and concluded that the language is

applicable to primary PCI programs because the language refers to requirements for internal and external review in the Chapter, thereby not limiting the exemption to elective PCI services.

Staff addressed Meritus's question about whether cases with MACE are excluded from being selected as part of the 10 percent of randomly selected cases at the May CSAC meeting, noting that these cases should not be excluded. Staff also stated that if a case has been reviewed internally already, due to MACE or for other reasons, then a second internal review of the case is not required. The proposed Chapter includes a detailed description of the selection of cases that Staff has concluded is sufficient.

In response to comments from MedStar Health and PRMC on the revised draft amendments posted in June 2015, Staff has added recommended language specifying that a review schedule will be published at least annually. Staff has not yet published a review schedule due to concerns about the timing of the final adoption of amendments to the regulations. However, Staff intends to post a schedule for Certificates of Ongoing Performance by the end of August 2015. With regard to the frequency of renewals, the regulations provide than a Certificate of Ongoing Performance may be granted for up to five years. Staff has concluded that flexibility is required and reasonable guidance is provided in the Chapter.

With regard to performance measures and the concerns expressed by PRMC regarding duplication of effort, Staff plans to review the MIEMSS application for Cardiac Interventional Center designation and will strive to minimize the reporting burden for hospitals. At this time, Staff does not recommend changes to the draft amendments. In response to Lifebridge Health's concerns about duplicate reporting, Staff notes that it does not anticipate routinely requesting patient records except as needed for auditing the ACC-NCDR registry and Society of Thoracic Surgeon's Adult Cardiac Surgery Database (STS-ACSD). Patient records also may be requested when necessary to complete a focused review or to determine whether a focused review is needed.

With regard to the requirements for internal and external peer review of cases, Staff notes that the number and percentage of cases to be reviewed for programs and individual interventionalists was intended to be consistent with the recommendations of the Commission's Clinical Advisory Group that was formed to provide advice on the development of regulations for PCI services and cardiac surgery. Staff again reviewed the final report of the Clinical Advisory Group from June 2013 and noted that it recommended that a minimum number of cases be included per physician for external review. Staff has revised the language in .07C(4)(c) of the proposed Chapter to include a requirement that a minimum of three cases per physician be reviewed semiannually, which would be six cases annually. Although the Clinical Advisory Group recommended 10 cases per physician for external review annually, Staff concluded that such a requirement would be expensive, and a review of fewer cases will be sufficient. Staff concludes that this changes will provide an opportunity to streamline the process of meeting requirements for external and internal peer review, as requested by some organizations, because the external review of cases for individual interventionalists may count toward the requirement for internal or external review of a minimum of ten cases or 10 percent of PCI case volume randomly selected for each interventionalist annually.

With regard to the use of 30-day risk adjusted all-cause mortality rates as a performance measure, Staff agrees that it will require linking with information from the Maryland Vital Statistics Administration. Staff notes that this performance measure was recommended by the Clinical Advisory Group and is already included in the current Chapter. Staff recognizes that few organizations are qualified to perform the work required to develop the statistics for 30-day risk adjusted all-cause mortality rates. However, Staff recommends that the performance measure continue to be included. Staff agrees that many of the measures suggested by Lifebridge Health are useful for evaluating the performance of hospitals. Staff anticipates that additional performance measures may be added to the Chapter in the future after consultation with the CSAC.

With regard to Dr. Deychak's comments on the CME requirement in .07D(7)(g), Staff recommends no changes. The Clinical Advisory Group recommended CME requirements consistent with current guidelines from the American College of Cardiology. The current Chapter is consistent with the Clinical Advisory Group's recommendations.

.08 External Peer Review

Regarding the draft amendments posted in April 2015 for informal public comment, MedStar Health commented that some of the standards in Regulation .08 are too prescriptive and recommended that the CSAC or a selected subcommittee be consulted to revise the language. MedStar Health also commented that, similar to Regulation .07, it is unclear under what circumstances annual or semi-annual review is required.

Dr. Julie Miller and Dr. Jeff Brinker also suggested minor changes to Regulation .08. These changes included removing the word "emergency" from the first question listed for external reviewers to answer in Section .08C, modifying another question in Section .08C to clarify the intent, and clarifying the data sources used for external review. Dr. David Zimrin also provided similar comments suggesting how to clarify the data sources referenced. In addition, Dr. Miller and Dr. Brinker requested clarification on whether the case volume requirement for external reviewers included cases performed during fellowship.

FMH recommended changing the definitions of partially successful and unsuccessful PCI procedures that were included in the draft Chapter posted for informal comment in April. In addition, FMH commented that the method for selecting cases is unnecessarily restrictive. FMH stated that an external peer review organization that is approved by MHCC should be capable of appropriately randomly selecting cases. FMH also commented that blinding of cases is burdensome, but it did not oppose the requirement.

With regard to the draft amendments posted in June 2015 for informal public comment, Lifebridge Health commented that the definition of procedure success in Paragraph .08C(1)(f) is inconsistent with the current ACCF/AHA/SCAI PCI Guidelines. These guidelines state that a minimum diameter stenosis of 10 percent, with an optimal goal of as close to zero percent as possible, should be the new benchmark for a lesion treated with coronary stenting. In addition, Lifebridge Health commented that board certification should be required for external reviewers

because it is a reasonable indirect marker of a physician's demonstrated knowledge and competence, regardless of when a physician completed his or her fellowship training.

Staff Response

Staff revised the language pertaining to reviews of PCI programs and interventionalists in Regulation .07 and Regulation .08 to clarify that annual review of individual interventionalists is required, but that a hospital has the option of accomplishing the required annual review through reviews conducted semi-annually or quarterly. In addition, the required annual review may be conducted internally or externally and may be combined with the required semi-annual external program review of five percent of total PCI cases.

Staff made changes to address all of the comments submitted by Dr. Julie Miller and Dr. Jeff Brinker, consistent with their recommendations. With regard to the case volume requirement, Staff decided not to count cases performed during fellowship and reduced the case volume requirement based on the expected number of cases that would be performed during fellowship.

With regard to FMH's request for greater flexibility in the case selection process, Staff notes that the CSAC recommended adopting a specific process that would be followed by everyone. Staff concludes that the process chosen is reasonable and may be accomplished with software commonly used by businesses, such as Microsoft Excel.

Staff agrees with Lifebridge Health that the determination of success by a reviewer should be consistent with current ACCF/AHA/SCAI PCI Guidelines and made changes to be consistent with these Guidelines.

Although Lifebridge Health proposes that all external reviewers used by hospitals to comply with COMAR 10.24.17 should be board certified, Staff has concluded that the exception included is reasonable. The Clinical Advisory Group specifically recommended the exception included for interventionalists with privileges at Maryland hospitals and is included in COMAR 10.24.17.

.09 Internal Review of Interventionalists

Staff did not receive comments on Regulation .09. However, following the posting of draft amendments for informal comment, Staff concluded that STEMI cases should not be excluded from internal review since exclusion of such cases from internal review was not recommended by CSAC members, who only recommended excluding STEMI cases from external review.

.11 Definitions

Cardiac Surgery and Open Heart Surgery

In response to the draft Chapter posted in April for informal comment, only MedStar Health commented on the definition of cardiac surgery. It proposed that the following ICD-9 procedure codes, 35.05, 35.06, 35.07, 35.08, and 35.09, which are an endovascular approach to heart valve repair, and 35.97 and 37.37 be excluded from the definition of cardiac surgery. MedStar Health noted that these are newer procedures and were only been added with the last update of COMAR 10.24.17 (effective August 2014). MedStar Health recommended that these codes be excluded because reimbursement policies do not treat them as cardiac surgery and the APR-DRG codes that define them align with PCI procedures.

In response to the draft Chapter posted for informal comment in June, UMMS recommended that the MHCC be extremely cautious about excluding cases from the volume calculations for cardiac surgery. It proposed that "whenever a procedure is conducted that requires the capacity and capability to perform cardiac surgery, it should be counted in the volume requirement. Jaime Brown, M.D., who is a cardiac surgeon affiliated with UMMS commented separately that he disagreed with the proposed classification system that separates open heart surgery from cardiac surgery, noting that the infrastructure required to perform safe cardiac surgery is extensive. He suggested that cardiac surgery be defined as follows:

> *A. Any procedure performed on the pericardium, heart or great vessels which is typically performed by a cardiac surgery team and,*
>
> *B. Any procedure performed on pericardium, heart or great vessels the potential complications of which would require both the infrastructure and specialty expertise of a cardiac surgery team for safe, appropriate and timely management.*

Dr. Brown also included a list of ICD-9 codes that are not included in the definition of cardiac surgery that meet his proposed definition. Please refer to his comments for the full list.

In contrast to UMMS and Dr. Brown, both MedStar Health and PRMC expressed support for the use of the term "open heart surgery" rather than the broader category of cases "cardiac surgery" when evaluating volume standards. MedStar Health noted that it is critical to count only "open heart surgery" cases due to the strong link between volume and quality specifically for open heart surgery. MedStar Health also stated that setting minimum volume standards based on "cardiac surgery" cases would significant reduce the number of open heart surgery cases necessary to operate a program and negatively affect the quality of care provided at those sites. MedStar Health further commented that with the last update of COMAR 10.24.17, effective August 18, 2014, there was already a significant reduction in the minimum number of open heart cases necessary to obtain and maintain a CON for cardiac surgery.

Staff Response

The purpose of separately defining open heart surgery and cardiac surgery is to promote quality programs and to have sufficient volume at cardiac surgery programs to allow for a more accurate and timely assessment of the quality of programs. The research that supports the volume standards of 100 and 200 open heart cardiac surgery cases is based on coronary artery bypass graft (CABG) procedures specifically, and the inclusion of many other types of cardiac surgery procedures requiring a different set of skills could dilute the intent of the volume standard. For this reason, as suggested by MedStar Health, Staff recommends that all transcatheter aortic valve replacement (TAVR) cases, a newer type of procedure often described as a hybrid procedure between interventional cardiology and cardiac surgery, should not be defined as cardiac surgery. In addition, Medicare has very specific requirements for hospitals that perform TAVR cases that want to be eligible for payment from Medicare, which in effect limit the number of providers of TAVR. The trends in case volume for TAVR generally may not be applicable to the consideration of new cardiac surgery programs which are less likely to perform TAVR procedures.

Commission staff worked closely with a subgroup of volunteers from the CSAC to evaluate the appropriate cardiac surgery codes that should be counted for the purpose of volume and the codes that should be restricted to hospitals with cardiac surgery programs. In many, but not all cases, the volunteers agreed on how to categorize codes. If any one of the volunteers proposed that a code be included as cardiac surgery, Staff conducted further research, noting how often the code showed up at hospitals with and without cardiac surgery programs. Staff then also contacted hospitals without cardiac surgery programs to find out if the use of the code was an error and whether in their view the procedure may be safely and appropriately performed at a hospital without cardiac surgery. The codes proposed for inclusion by Dr. Brown are ones discussed among the volunteers and carefully considered by Staff.

Cardiac procedure codes that encompass a range of surgical procedures that may be open or closed or that may be performed by non-cardiac surgeons safely are not included in the definition of cardiac surgery, in order to most efficiently and accurately identify cases that should count for the volume standards and utilization projection. In addition, including codes that may be performed by non-cardiac surgeons would result in an unintentional expansion of the scope of CON regulation. Once the use of ICD-10 codes has been implemented, the procedure codes will be re-evaluated. The ICD-10 codes allow for greater discrimination among procedures and using these codes may address some concerns about properly accounting for cases.

Percutaneous Coronary Intervention (PCI)

In response to the draft amendments posted in April, MedStar Health stated that the definition for PCI needed to be updated because some of the ICD-9 codes are no longer valid.

Staff Response

Staff updated the definition of PCI for the draft amendments posted in June. No comments were submitted on the revised definition.

Definitions for Emergency PCI and Primary PCI

MedStar Health expressed concern about the definition of emergency PCI and properly distinguishing it from primary PCI. In addition, it expressed concern regarding the definition for primary PCI operator.

Staff Response

Staff reviewed these definitions again and concluded that no changes are required to address MedStar Health's concerns. However, Staff eliminated use of the term primary PCI operator, which appeared only once in the regulation, and replaced it with equivalent language used more frequently in the regulation. With regard to the use of emergency PCI and primary PCI, Staff has concluded that these terms are used consistent with the terminology historically used, which usually includes the use of emergency PCI and primary PCI as equivalent. In addition, at the May 2015 CSAC meeting, the member consensus was that no change is required.

.10 Utilization Projection Methodology for Open Heart Surgery

Staff did not receive comments on this section. However, Staff made changes in Regulation .10 consistent with the decision to define cardiac surgery more broadly and to count only open heart surgery cases when making utilization projections for cardiac surgery for reasons explained under the Staff response to comments on the definitions of cardiac surgery and open heart surgery included in Regulation .09.

Other Comments

With regard to the draft amendments posted in April 2015 for informal public comment, Meritus proposed that a timeframe be specified for preparing for a focused review.

UMMS, PRMC, and MedStar Health all requested that Staff should further streamline the requirements for a Certificate of Ongoing Performance for hospitals that perform both cardiac surgery and PCI services.

A representative for the ACTION Registry- GWTG commented that the draft regulations neglected to include the word "Registry" where the name appears in COMAR 10.24.17.

Staff Response

With regard to Meritus's comments, Commission staff concludes that a timeframe cannot be readily specified for a hospital to prepare for a focused review because of the range of possible circumstances. Staff explained its conclusion at the May 2015 CSAC meeting, and no additional comments were submitted regarding this issue.

Staff concludes that it is necessary to handle reviews for Certificates of Ongoing Performance of PCI programs separately from reviews for cardiac surgery programs for at least the first review cycle. However, Staff will consider ways to streamline the process for future

review cycles and changing the wording of the regulations is not required to implement this approach. In addition, Staff corrected the reference to the ACTION Registry-GWTG, as suggested.

Other Proposed Changes

Staff has made other non-substantive and minor corrections throughout the document that are not described here.